

REMARKS

Claims 1-57 are pending in the application. Claims 1-14, 16-20, 22, 23, 25-43, 46-51, 54 and 56 stand rejected. Claims 15, 21, 24, 44, 45, 52, 53, 55 and 57 were objected to, but were indicated to be allowable if amended to incorporate the base claim from which each depends and any intervening claims. In this response, claims 1, 12, 22, 33 and 51 have been amended and new claims 58-88 are presented for consideration. Entry of the present amendment and a Notice of Allowance for the present application is respectfully requested in view of the following remarks.

The original oath was objected to as being defective for including non-initialed and/or non-dated alterations. Please find enclosed herewith a new oath identifying this application by serial number and filing date in compliance with 37 CFR 1.67(a).

Claims 12 and 51 were objected to for various informalities as set forth in the Office Action. Claims 12 and 51 have been amended to address the informalities, and withdrawal of the objection to the same is respectfully requested.

Claims 1, 3, 7, 13-14, 16-17, 22, 26-27, 33-34, 37 40, and 46 were rejected under 35 U.S.C. § 102(b) as being anticipated by EP Publication No. 0 867 149 A1 to Jobe. It is respectfully submitted that Jobe does not anticipate the claims for the reasons that follow, and withdrawal of this basis of the rejection is respectfully requested.

Amended claim 1 recites “a plate having a generally triangular shape” and further recites “wherein said plate includes a profile along said upper node and said pair of lower nodes adapted to conform to the anterior margin of at least one of the L5 and S1 vertebrae.” The triangular shape minimizes potential interference of the plate with the delicate anatomical structures in the L5-S1 region, while the profile allows the plate to be securely positioned along the L5 and S1 vertebrae to resist tensile and bending forces, and also to minimize the anterior protrusion of the plate from the L5- S1 vertebrae. This profile also assists in transferring the load of the spinal column from the L5 vertebra to the S1 vertebra.

This combination of features is not disclosed in Jobe. Rather, Jobe provides a plate where conformance to bone surfaces is not required since the plate is adapted for securing bone segments that are subject to forces tending to spread the bone sections apart or cause

lateral slippage of bone sections along a fracture line, such as with facial and cranial bone sections and other bones that do not carry large loads. *See* col. 1, line 56 to col. 2, line 10 and also col. 4, line 49 to col. 5, line 1. Jobe does not disclose a plate having a profile adapted to conform to the anterior margin of at least one of the L5 and S1 vertebrae. Accordingly, claim 1 distinguishes Jobe and withdrawal of the rejection of claim 1 is respectfully requested.

Claims 3, 7 and 13 depend from claim 1 and are allowable at least for the reasons provided above and for other reasons. For example, claim 3 recites that the plate “includes at least one spike extending from a posterior face of said plate positionable into the L5 vertebra.” Jobe discloses a longitudinal flange or rib 30, but does not disclose a spike. Claim 13 recites “wherein said plate includes a retaining element adjacent each of said upper hole and said first and second lower holes, each of said retaining elements having a first form wherein a screw is insertable into the adjacent hole and being formable to a second form wherein said retaining element extends over the adjacent hole.” While Jobe discloses replacing post device 14a with a screw or other fastener, there is no disclosure of a plate including retaining elements formable over the adjacent hole. Accordingly, withdrawal of the rejection of claim 3, 7 and 13 is respectfully requested.

Claim 14 recites “a plate” and “a retaining element extending from said upper face adjacent said at least one hole, said retaining element having a first form wherein a screw is insertable into the at least one hole and being formable to a second form wherein at least a portion of said retaining element extends over said at least one hole.” These features are not disclosed in Jobe. The Office Action asserts that claim 14 is anticipated since Jobe that “if additional security is desired, plate member 12 may be secured to bone by replacing one of the post devices 14, for example post device 14a shown in Figure 3, with a screw or other suitable fastener which securely engages the walls of hole 24 to attach the plate member to the surface of the bone section.” However, neither this portion of Jobe, nor any other portion of Jobe, discloses a retaining element extending from an upper surface of the plate having a first form for screw insertion and second form extending over the hole. Accordingly, withdrawal of the rejection of claim 14 is respectfully requested.

Claims 16 and 17 depend from claim 14 and were also rejected as being anticipated by Jobe. These claims are allowable at least for the reasons provided above with respect to claim 14.

Amended claim 22 recites “a plate having a generally triangular shape with an upper node positionable along an upper vertebra and a pair of lower nodes positionable along a lower vertebra; an upper hole in the plate at the upper node to receive a screw for engaging the upper vertebra; a first lower hole in the plate through one of the lower nodes to receive a screw for engaging the lower vertebra and a second lower hole in the plate through the other of the lower nodes to receive a screw for engaging the lower vertebra, wherein said upper hole extends through said plate along an axis oriented away from said pair of lower nodes.” Jobe, in contrast, only discloses posts 14 that are oriented toward one another or are oriented perpendicular to the plate. Accordingly, claim 22 distinguishes Jobe, and withdrawal of this basis of the rejection is respectfully requested.

Claims 26 and 27 depend from claim 22 and were also rejected as being anticipated by Jobe. These claims are allowable at least for the reasons provided above with respect to claim 22, and also for the reasons provided above with respect to claim 14.

Amended claim 33 recites “a plate having a general triangular shape, said plate having an upper hole near an upper vertex through which a screw is passed for securing said plate to the L5 vertebra, and a pair of lower holes situated near respective ones of first and second lower vertices of said plate, each of said pair of lower holes having a screw passed therethrough to secure said plate to the S1 vertebra, wherein said plate includes a profile between said upper vertex and said first and second lower vertices adapted to conform to the anterior margin of at least one of the L5 and S1 vertebrae.” As discussed above with respect to claim 1, this combination of features is not disclosed by Jobe, and withdrawal of the rejection of claim 33 is respectfully requested.

Claims 34, 37, 40, and 46 depend from claim 33 and were also rejected as being anticipated by Jobe. These claims are allowable at least for the reasons provided above with respect to claim 33, and also for other reasons. For example, claim 34 recites that the plate includes “a posterior face having a protrusion extending along at least part of the

width” of the plate. Jobe, on the other hand, only discloses flange or rib 30 extending along the length of the plate between the adjacent bone segments. There is no disclosure of a protrusion along at least part of the width of the plate. Claim 37 recites “wherein said plate includes a posterior face having an edge about said plate, said posterior face including an anchoring point extending therefrom adjacent said upper vertex” in addition to the hole for the screw recited in claim 33. There is no disclosure in Jobe of both a post/screw and an anchoring point near the upper vertex of the plate. Jobe also fails to disclose the means for blocking screws recited in claim 46 that includes “a retaining element which can be screwed onto the plate.”

Claims 2, 4-6, 8-9, 12, 20, 25, 38, 41, 43, 48, 51, 54 and 56 were rejected as being unpatentable over Jobe in view of U.S. Patent No. 6,306,139 to Fuentes. Fuentes is potential prior art under 35 USC §102(e). Applicants reserve the right to swear behind the filing date of Fuentes with an affidavit under 37 CFR §1.131 in this application or in any continuing application.

Assuming Fuentes were prior art, the combination of Jobe and Fuentes does disclose or suggest claims 2, 4-6, 8-9, 12, 20, 25, 38, 41, 43, 48, 51, 54 and 56. Claims 2, 4-6, 8-9 and 12 depend from claim 1, and are allowable at least because claim 1 is allowable for the reasons provided above and for other reasons. For example, for claim 5 the Office Action correctly points out that the inferior margin of the L5 vertebrae is not being claimed. What is being claimed in claim 5, however, is “a protrusion extending from said posterior face” adapted to contact the inferior margin of the L5 vertebra. Neither Jobe nor Fuentes disclose or suggest this feature since, as discussed above, Jobe only disclose flange or rib 30 that extends longitudinally between vertebrae. With regard to claim 6, Fit recites that the lower nodes each have a thickened portion adapted to conform to the profile of the anterior face of the S1 vertebra.” Fuentes may generally disclose modifying a thickness of the plate, but there is no disclosure or suggestion of providing lower nodes of a triangular plate with thickened portions as claimed in claim 6.

Claim 20 depends from claim 14, and is allowable at least for the reasons that claim 14 is allowable as provided above. Claim 25 depends from claim 22, and is allowable at least for the reasons that claim 22 is allowable as provided above. Claims

38, 41, 43 and 48 depend from claim 33, and are allowable at least for the reasons that claim 33 is allowable as provided above.

The combination of Jobe and Fuentes also fails to disclose or suggest claims 51, 54 and 56. Amended claim 51 recites “an instrument including: a plate holding portion coupled to said plate and being configured to establish and maintain a defined relative position between said instrument and said plate; a shaft having a proximal handle portion and a distal end supporting said plate holding portion; and a support extending from said shaft....” The instrument 30 in Fuentes, in contrast, does not disclose a support extending from the shaft in addition to a plate holding portion at the distal end of the shaft. Fuentes only discloses a guide block 32 that is engaged to the plate. Bores 33 through the guide block 32 are thus necessarily adjacent to the plate, and block 32 can only provide guidance along the distal portions of the instruments. Claim 51, in contrast, recites an instrument that includes a support extending from the shaft in addition to a plate holding portion at a distal end of the shaft. Accordingly, greater angulation capabilities and support remote from the distal ends of the drill is obtained with the system recited in claim 51. Since Fuentes fails to disclose or suggest claim 51, claim 51 is allowable along with claims 54 and 56 depending therefrom.

Claims 10, 11, 18, 19, 23, 42 and 47 were also rejected as being unpatentable over Jobe in view of U.S. Patent No. 6,306,139 to Fuentes. The Office Action asserts that, with respect to claims 10, 11, 23, 42 and 47, it would have been an obvious matter of design choice to make the retaining element with a triangular or circular shape, since such modification would have involved mere change in the shape of a component.” To establish a prima facie case of obviousness, there must be some reason, suggestion or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the references. As admitted in the Office Action, the references do not disclose circular or triangular retaining elements. In fact, Fuentes teaches away from providing circular retaining elements since it discloses an anti-extraction device that is rotated about its axis from a first position for screw insertion to a second position that obturates access to the screw holes. A circular retaining element sized to block the screw holes could not rotated about its axis between blocking and unblocking positions relative

to the plate holes. The combination of Jobe and Fuentes fails to teach or suggest a circular retaining element. With regard to claims 10, 23, and 47 directed to a triangular retaining element, the retaining element has the same shape as the plate, allowing the dimensions of the plate and thus intrusion into the adjacent anatomy by the plate to be minimized while providing screw retention. The combination of Jobe and Fuentes fails to teach suggest a retaining element with a geometry that matches the plate geometry. Accordingly, claims 10, 11, 23, 42 and 47 are allowable.

With respect to claim 18 and 19, neither Jobe nor Fuentes discloses retaining elements integrally formed with an upper face of the plate. Fuentes teaches away from such a connecting element since it teaches providing a mobile flap that can be moved relative to the plate to allow screw insertion and anti-extraction. Accordingly, claim 18 and 19 distinguish the combination of Jobe and Fuentes and are allowable.

Claim 28 was rejected as being unpatentable over U.S. Patent No. 6,045,552 to Zucherman et al in view of Jobe. Zucherman discloses a plate positionable on the anterior face of the L5-S1 vertebrae with keels extending from the lower surface of the plate and into the L5 and S1 vertebrae. In Fig. 2 of Zucherman, the plate has a lower, triangular shaped end portion with the pointed end of the triangular portion oriented downwardly along S1. The Office Action asserts that Jobe discloses a triangular-shaped plate “capable” of being positioned along the anterior face of the S1 vertebra. The Office Action further asserts that Jobe teaches that three screws may be installed in the upper and lower nodes each through a single hole in the plate. Jobe does not provide any teaching or suggestion regarding any particular orientation of the triangular plate disclosed therein. Contrary to the assertion in the Office Action, Jobe does not disclose “upper and lower nodes” since the orientation of the plate in Jobe is irrelevant so long as the plate extends across the fracture line between the bone segments. Accordingly, the combination of Zucherman and Jobe would, at most, suggest orienting the single node of the triangular plate downwardly along S1. In contrast, claim 28 is a method claim and recites “installing a generally triangular-shaped plate having an upper node along the face of the L5 vertebra and a pair of lower nodes along the anterior face of the S1 vertebra....”

There is no suggestion in Zucherman or Jobe of installing a triangular-shaped plate as claimed in claim 28, and allowance of claim 28 is respectfully requested.

Claims 29-32 were rejected as being unpatentable over Zucherman et al. in view of Jobe as applied to claim 28, and further in view of Fuentes. Claims 29 –32 depend from claim 28 and are allowable at for the reasons claim 28 is allowable.

Claims 35-36 were rejected as being unpatentable over Jobe as applied to claim 33, and further in view of Zucherman. Claims 35 and 36 depend from claim 33, and are allowable at least for the reasons claim 33 is allowable as discussed above.

Claim 39 was rejected as being unpatentable over Jobe. Claim 39 recites that “said pair of lower holes have an oblong shape extending in the direction toward said vertex.” As discussed in the specification on page 11, first paragraph, the oblong holes provide freedom for locating screws in S1 and allow post-implantation adaptation to patient morphology. The features recited in claim 39 are thus not merely a design choice, and are not disclosed or suggested in Jobe. To establish a prima facie case of obviousness, there must be some reason, suggestion or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the references. It is submitted that Jobe does not contain the required reason, suggestion or motivation to modify the device in Jobe as set forth in the Office Action. No reference has been cited that teaches or suggests the features in claim 39. If the rejections in the Office Action in this regard are based on facts within the personal knowledge of the Examiner, then the Applicant respectfully requests an affidavit from the Examiner in support of the rejection so that the same may be considered and rebutted by the Applicant.

Claims 49 and 50 were rejected as being unpatentable over Zucherman in view of Jobe. Zucherman discloses a plate positionable on the anterior face of the L5-S1 vertebrae with keels extending from the lower surface of the plate and into the L5 and S1 vertebrae. In Fig. 2 of Zucherman, the plate has a lower, triangular shaped end portion with the pointed end of the triangular portion oriented downwardly along S1. Jobe does not provide any teaching or suggestion regarding any particular orientation of the triangular plate disclosed therein, only that the plate extends across the fracture line between the bone segments. Accordingly, the combination of Zucherman and Jobe would, at most, suggest

orienting the single node of the triangular plate downwardly along S1. In contrast, claim 49 recites “a plate having a triangular shape, said plate having an upper vertex positionable over L5 and lower vertices positionable over S1, each of said vertices having a hole formed therethrough; three screws, each of said screws positioned through a corresponding one of said holes to secure said plate to L5 and S1” There is no suggestion in Zucherman or Jobe of a plate having a triangular shape as recited in claim 49, and allowance of claim 49 and 50 is respectfully requested.

New claims 58-84 are presented in this response for consideration by the Examiner. Claim 58 presents original dependent claim 15 in independent form, and is allowable as indicated in the Office Action. Claim 59-64 depend from claim 58 and are also allowable.

New claim 65 presents original dependent claim 24 in independent form, and is allowable as indicated in the Office Action. Claim 66 depends from claim 65 and is also allowable.

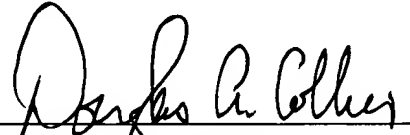
New claim 67 presents original dependent claim 45 in independent form, and is allowable as indicated in the Office Action. Claims 68-78 depend from claim 67 and are also allowable.

New claim 79 recites “a plating apparatus for the spine, comprising: a plate having a general triangular shape, said plate having an upper hole near an upper vertex through which a screw is passed for securing said plate to the L5 vertebra, and a pair of lower holes situated near respective ones of first and second lower vertices of said plate, each of said pair of lower holes having a screw passed therethrough to secure said plate to the S1 vertebra; a retaining element attachable to a central hole in said plate, said retaining element configured to at least partially cover said upper hole and said pair of lower holes, said retaining element including an elastic tongue with a stud extending from a posterior face of said retaining element, said stud insertable in a receiving seat formed on an anterior face of said plate.” Claim 79 is allowable along with claims 80-88 depending therefrom.

In view of the foregoing remarks, reconsideration of the present application as amended is respectfully requested. These amendments and remarks do not introduce new

matter or limit the scope of coverage available under the doctrine of equivalents. Action towards a notice of allowance for this application, including claims 1-88 is hereby solicited. The undersigned would welcome an interview with the Examiner to resolve any outstanding issues that might arise with respect to the present application.

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